ANNEX A: PRIMARY AND SECONDARY LEGISLATION

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I Primary Legislation

(Selected provisions of the EC Treaty having a bearing on Intellectual Property)

Article 2

The Community shall have as its task, by establishing a common market and an economic and monetary union and by implementing common policies or activities referred to in Articles 3 and 4, to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and non-inflationary growth, a high degree of competitiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States.

Article 3

1. For the purposes set out in Article 2, the activities of the Community shall include, as provided in this Treaty and in accordance with the timetable set out therein:

(a) the prohibition, as between Member States, of customs duties and quantitative restrictions on the import and export of goods, and of all other measures having equivalent effect;

(b) a common commercial policy;

(c) an internal market characterised by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital; …

(g) a system ensuring that competition in the internal market is not distorted;

(h) the approximation of the laws of Member States to the extent required for the functioning of the common market; …

Article 10 (formerly Article 5)

Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community. They shall facilitate the achievement of the Community's tasks.

They shall abstain from any measure which could jeopardise the attainment of the objectives of this Treaty.

Article 12 (formerly Article 6)

Within the scope of application of this Treaty, and without prejudice to any special provisions contained therein, any discrimination on grounds of nationality shall be prohibited.

The Council, acting in accordance with the procedure referred to in Article 251, may adopt rules designed to prohibit such discrimination.

Article 16 (formerly Article 7d)

Without prejudice to Articles 73, 86 and 87, and given the place occupied by services of general economic interest in the shared values of the Union as well as their role in promoting social and territorial cohesion, the Community and the Member States, each within their respective powers and within the scope of application of this Treaty, shall take care that such services operate on the basis of principles and conditions which enable them to fulfil their missions.

Article 28 (formerly Article 30)

Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 29 (formerly Article 34)

Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.

Article 30 (formerly Article 36)

The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

II Secondary Legislation (Selected Regulations and Directives relating to Intellectual Property Rights and the Rules on Competition)

A Intellectual Property Rights involving Technology

1 Supplementary Protection Certificates

Council Regulation EEC/1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products
The Council of the European Communities,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,
Having regard to the proposal from the Commission (1),
In cooperation with the European Parliament (2),
Having regard to the opinion of the Economic and Social Committee (3),
Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;
Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection top encourage such research;
Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;
Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;
Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;
Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;
Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;
Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusively from the time the medicinal product in question first obtains authorization to be placed on the market in the Community;
Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account;

whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;
Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level;
Whereas the transitional arrangements applicable to applications for certificates filed and to certificates granted under national legislation prior to the entry into force of this Regulation should be defined;
Whereas special arrangements should be allowed in Member States whose laws introduced the patentability of pharmaceutical products only very recently;
Whereas provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,
has adopted this regulation:

Article 1

Definitions

For the purposes of this Regulation:
(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;
(c) 'basic patent' means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
(d) 'certificate' means the supplementary protection certificate.

Article 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC (4) or Directive 81/851/EEC (5) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Article 3

1 Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
(a) the product is protected by a basic patent in force;
(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.

Article 4

Subject matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

Article 5

Effects of the certificate

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

Article 6

Entitlement to the certificate

The certificate shall be granted to the holder of the basic patent or his successor in title.

Article 7

Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3 (b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

Article 8

Content of the application for a certificate

1. The application for a certificate shall contain:
(a) a request for the grant of a certificate, stating in particular:
(i) the name and address of the applicant;
(ii) if he has appointed a representative, the name and address of the representative;
(iii) the number of the basic patent and the title of the invention;
(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3 (b) and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization;
(b) a copy of the authorization to place the product on the market, as referred to in Article 3 (b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive EEC/65/65 or Article 5a of Directive EEC/851/81;
(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

2. Member States may provide that a fee is to be payable upon application for a certificate.

Article 9

Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3 (b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:
(a) the name and address of the applicant;
(b) the number of the basic patent;
(c) the title of the invention;

(d) the number and date of the authorization to place the product on the market, referred to in Article 3 (b), and the product identified in that authorization;
(e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

Article 10

Grant of the certificate or rejection of the application

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9 (1) shall grant the certificate.

2. The authority referred to in Article 9 (1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9 (1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9 (1) is to grant certificates without verifying that the conditions laid down in Article 3 (c) and (d) are met.

Article 11

Publication

1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the following information:
(a) the name and address of the holder of the certificate;
(b) the number of the basic patent;
(c) the title of the invention;
(d) the number and date of the authorization to place the product on the market referred to in Article 3 (b) and the product identified in that authorization;
(e) where relevant, the number and date of the first authorization to place the product on the market in the Community;
(f) the duration of the certificate.

2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9 (1). The notification shall contain at

least the information listed in Article 9 (2).

Article 12

Annual fees

Member States may require that the certificate be subject to the payment of annual fees.

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a perid equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

Article 14

Expiry of the certificate

The certificate shall lapse:
(a) at the end of the period provided for in Article 13;
(b) if the certificate-holder surrenders it;
(c) if the annual fee laid down in accordance with Article 12 is not paid in time;
(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place on the market in accordance with Directive EEC/65/65 or Directive EEC/851/81.
The authority referred to in Article 9(1) may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate

1. The certificate shall be invalid if:
(a) it was granted contrary to the provisions of Article 3;
(b) the basic patent has lapsed before its lawful term expires;
(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the renovation of the corresponding basic patent.

Article 16

Notification of lapse or invalidity

If the certificate lapses in accordance with Article 14 (b), (c) or (d) or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9 (1).

Article 17

Appeals

The decisions of the authority referred to in Article 9 (1) or of the body referred to in Article 15 (2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

Article 18

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.

2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

Article 19

Transitional provisions

1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.
In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.
In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.

Article 20

This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation in the Official Journal of the European Communities.

Article 21

In those Member States whose national law did not on 1 January 1990 provide for the patentability of pharmaceutical products, this Regulation shall apply five years after the entry into force of this Regulation. Article 19 shall not apply in those Member States.

Article 22

Where a certificate is granted for a product protected by a patent which, before the date on which this Regulation enters into force, has had its term extended or for which such extension was applied for, under national patent law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.

FINAL PROVISION

Article 23

Entry into force

This Regulation shall enter into force six months after its publication in the Official Journal of the European Communities.

2 Biotechnological Inventions

Directive EC/44/98 of the European Parliament and of The Council of 6 July 1998 on the legal protection of biotechnological inventions

The European Parliament and the Council of the European Union,
Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,
Having regard to the proposal from the Commission (1),
Having regard to the opinion of the Economic and Social Committee (2),
Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),
(1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;
(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;
(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;
(4) Whereas following the European Parliament's rejection of the joint text, approved by the Conciliation Committee, for a European Parliament and Council Directive on the legal protection of biotechnological inventions (4), the European Parliament and the Council have determined that the legal protection of biotechnological inventions requires clarification;
(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;
(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or whereas national case-law interpreting such legislation develops differently;
(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;
(8) Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;
(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said

uncertainty;
(10) Whereas regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground; whereas the patent system should be used to encourage research into, and the application of, such processes;
(11) Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world; whereas the patent system should likewise be used to encourage research in these fields; whereas international procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned should be promoted;
(12) Whereas the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) (5) signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology;
(13) Whereas the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such, such principles being intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin, to the scope of protection conferred by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions and lastly to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely;
(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;
(15) Whereas no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes a priori the patentability of biological matter;
(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;
(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in

the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;
(18) Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan` diseases, the Community and the Member States have a duty to respond adequately to this problem;
(19) Whereas account has been taken of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission;
(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;
(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;
(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;
(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;
(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;
(25) Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms;
(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;
(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;
(28) Whereas this Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a patented

product;
(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;
(30) Whereas the concept 'plant variety` is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesss individuality and is clearly distinguishable from other varieties;
(31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;
(32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;
(33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological;
(34) Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent law;
(35) Whereas this Directive shall be without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability;
(36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;
(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive;
(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;
(39) Whereas ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;
(40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality;

whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;
(41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;
(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;
(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;
(44) Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law;
(45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability;
(46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself;
(47) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorise the farmer to use the product of his harvest for further multiplication or propagation on his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (6);
(48) Whereas only the fee envisaged under Community law relating to plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer;
(49) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against a breeder who has developed a plant variety incorporating the protected invention if the latter fails to adhere to his commitments;
(50) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use protected livestock for agricultural purposes;

(51) Whereas the extent and the conditions of that second derogation must be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;
(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;
(53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;
(54) Whereas Article 34 of the TRIPs Agreement contains detailed provisions on the burden of proof which is binding on all Member States; whereas, therefore, a provision in this Directive is not necessary;
(55) Whereas following Decision 93/626/EEC (7) the Community is party to the Convention on Biological Diversity of 5 June 1992; whereas, in this regard, Member States must give particular weight to Article 3 and Article 8(j), the second sentence of Article 16(2) and Article 16(5) of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive;
(56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity`,
have adopted this Directive:

CHAPTER I Patentability

Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 2

1. For the purposes of this Directive,
(a) 'biological material` means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
(b) 'microbiological process` means any process involving or performed upon or resulting in microbiological material.

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of 'plant variety` is defined by Article 5 of Regulation EC/2100/94.

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4

1. The following shall not be patentable:
(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural

element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 7

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

CHAPTER II Scope of protection

Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.

Article 10

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 11

1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

CHAPTER III Compulsory cross-licensing

Article 12

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.
2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

CHAPTER IV Deposit, access and re-deposit of a biological material

Article 13

1. Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:
(a) the biological material has been deposited no later than the date on which the patent application was filed with a recognised depositary institution. At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty`, shall be recognised;
(b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;
(c) the patent application states the name of the depository institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:
(a) up to the first publication of the patent application, only to those persons who are authorised under national patent law;
(b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;
(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:
(a) not to make it or any material derived from it available to third parties; and
(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

Article 14

1. If the biological material deposited in accordance with Article 13 ceases to be available from the recognised depositary institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

2. Any new deposit shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited.

CHAPTER V Final provisions

Article 15

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof.
When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 16

The Commission shall send the European Parliament and the Council:
(a) every five years as from the date specified in Article 15(1) a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded;
(b) within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable;
(c) annually as from the date specified in Article 15(1), a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

Article 17

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 18

This Directive is addressed to the Member States.

3 Industrial Designs

Directive EC/71/98 of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs

The European Parliament and the Council of the European Union,
Having regard to the Treaty establishing the European Community and in particular Article 100a thereof,
Having regard to the proposal by the Commission (1),
Having regard to the opinion of the Economic and Social Committee (2),
Acting in accordance with the procedure laid down in Article 189b of the Treaty (3), in the light of the joint text approved by the Conciliation Committee on 29 July 1998,
(1) Whereas the objectives of the Community, as laid down in the Treaty, include laying the foundations of an ever closer union among the peoples of Europe, fostering closer relations between Member States of the Community, and ensuring the economic and social progress of the Community countries by common action to eliminate the barriers which divide Europe; whereas to that end the Treaty provides for the establishment of an internal market characterised by the abolition of obstacles to the free movement of goods and also for the institution of a system ensuring that competition in the internal market is not distorted; whereas an approximation of the laws of the Member States on the legal protection of designs would further those objectives;
(2) Whereas the differences in the legal protection of designs offered by the legislation of the Member States directly affect the establishment and functioning of the internal market as regards goods embodying designs; whereas such differences can distort competition within the internal market;
(3) Whereas it is therefore necessary for the smooth functioning of the internal market to approximate the design protection laws of the Member States;
(4) Whereas, in doing so, it is important to take into consideration the solutions and the advantages with which the Community design system will provide undertakings wishing to acquire design rights;
(5) Whereas it is unnecessary to undertake a full-scale approximation of the design laws of the Member States, and it will be sufficient if approximation is limited to those national provisions of law which most directly affect the functioning of the internal market; whereas provisions on sanctions, remedies and enforcement should be left to national law; whereas the objectives of this limited approximation cannot be sufficiently achieved by the Member States acting alone;
(6) Whereas Member States should accordingly remain free to fix the procedural provisions concerning registration, renewal and invalidation of design rights and provisions concerning the effects of such invalidity;
(7) Whereas this Directive does not exclude the application to designs of national or Community legislation providing for protection other than that conferred by registration or publication as design, such as legislation relating to unregistered design rights, trade marks, patents and utility models, unfair competition or civil liability;
(8) Whereas, in the absence of harmonisation of copyright law, it is important to establish the principle of cumulation of protection under specific registered design protection law and under copyright law, whilst leaving Member States free to establish the extent of

copyright protection and the conditions under which such protection is conferred;
(9) Whereas the attainment of the objectives of the internal market requires that the conditions for obtaining a registered design right be identical in all the Member States; whereas to that end it is necessary to give a unitary definition of the notion of design and of the requirements as to novelty and individual character with which registered design rights must comply;
(10) Whereas it is essential, in order to facilitate the free movement of goods, to ensure in principle that registered design rights confer upon the right holder equivalent protection in all Member States;
(11) Whereas protection is conferred by way of registration upon the right holder for those design features of a product, in whole or in part, which are shown visibly in an application and made available to the public by way of publication or consultation of the relevant file;
(12) Whereas protection should not be extended to those component parts which are not visible during normal use of a product, or to those features of such part which are not visible when the part is mounted, or which would not, in themselves, fulfil the requirements as to novelty and individual character; whereas features of design which are excluded from protection for these reasons should not be taken into consideration for the purpose of assessing whether other features of the design fulfil the requirements for protection;
(13) Whereas the assessment as to whether a design has individual character should be based on whether the overall impression produced on an informed user viewing the design clearly differs from that produced on him by the existing design corpus, taking into consideration the nature of the product to which the design is applied or in which it is incorporated, and in particular the industrial sector to which it belongs and the degree of freedom of the designer in developing the design;
(14) Whereas technological innovation should not be hampered by granting design protection to features dictated solely by a technical function; whereas it is understood that this does not entail that a design must have an aesthetic quality; whereas, likewise, the interoperability of products of different makes should not be hindered by extending protection to the design of mechanical fittings; whereas features of a design which are excluded from protection for these reasons should not be taken into consideration for the purpose of assessing whether other features of the design fulfil the requirements for protection;
(15) Whereas the mechanical fittings of modular products may nevertheless constitute an important element of the innovative characteristics of modular products and present a major marketing asset and therefore should be eligible for protection;
(16) Whereas a design right shall not subsist in a design which is contrary to public policy or to accepted principles of morality; whereas this Directive does not constitute a harmonisation of national concepts of public policy or accepted principles of morality;
(17) Whereas it is fundamental for the smooth functioning of the internal market to unify the term of protection afforded by registered design rights;
(18) Whereas the provisions of this Directive are without prejudice to the application of the competition rules under Articles 85 and 86 of the Treaty;
(19) Whereas the rapid adoption of this Directive has become a matter of urgency for a number of industrial sectors; whereas full-scale approximation of the laws of the Member

States on the use of protected designs for the purpose of permitting the repair of a complex product so as to restore its original appearance, where the product incorporating the design or to which thedesign is applied constitutes a component part of a complex product upon whose appearance the protected design is dependent, cannot be introduced at the present stage; whereas the lack of full-scale approximation of the laws of the Member States on the use of protected designs for such repair of a complex product should not constitute an obstacle to the approximation of those other national provisions of design law which most directly affect the functioning of the internal market; whereas for this reason Member States should in the meantime maintain in force any provisions in conformity with the Treaty relating to the use of the design of a component part used for the purpose of the repair of a complex product so as to restore its original appearance, or, if they introduce any new provisions relating to such use, the purpose of these provisions should be only to liberalise the market in such parts; whereas those Member States which, on the date of entry into force of this Directive, do not provide for protection for designs of component parts are not required to introduce registration of designs for such parts; whereas three years after the implementation date the Commission should submit an analysis of the consequences of the provisions of this Directive for Community industry, for consumers, for competition and for the functioning of the internal market; whereas, in respect of component parts of complex products, the analysis should, in particular, consider harmonisation on the basis of possible options, including a remuneration system and a limited term of exclusivity; whereas, at the latest one year after the submission of its analysis, the Commission should, after consultation with the parties most affected, propose to the European Parliament and the Council any changes to this Directive needed to complete the internal market in respect of component parts of complex products, and any other changes which it considers necessary;
(20) Whereas the transitional provision in Article 14 concerning the design of a component part used for the purpose of the repair of a complex product so as to restore its original appearance is in no case to be construed as constituting an obstacle to the free movement of a product which constitutes such a component part;
(21) Whereas the substantive grounds for refusal of registration in those Member States which provide for substantive examination of applications prior to registration, and the substantive grounds for the invalidation of registered design rights in all the Member States, must be exhaustively enumerated,
have adopted this directive:

Article 1

Definitions

For the purpose of this Directive:
(a) 'design` means the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation;
(b) 'product` means any industrial or handicraft item, including inter alia parts intended to be assembled into a complex product, packaging, get-up, graphic symbols and typographic typefaces, but excluding computer programs;

(c) 'complex product` means a product which is composed of multiple components which can be replaced permitting disassembly and reassembly of the product.

Article 2

Scope of application

1. This Directive shall apply to:
(a) design rights registered with the central industrial property offices of the Member States;
(b) design rights registered at the Benelux Design Office;
(c) design rights registered under international arrangements which have effect in a Member State;
(d) applications for design rights referred to under (a), (b) and (c).

2. For the purpose of this Directive, design registration shall also comprise the publication following filing of the design with the industrial property office of a Member State in which such publication has the effect of bringing a design right into existence.

Article 3

Protection requirements

1. Member States shall protect designs by registration, and shall confer exclusive rights upon their holders in accordance with the provisions of this Directive.

2. A design shall be protected by a design right to the extent that it is new and has individual character.

3. A design applied to or incorporated in a product which constitutes a component part of a complex product shall only be considered to be new and to have individual character:
(a) if the component part, once it has been incorporated into the complex product, remains visible during normal use of the latter, and
(b) to the extent that those visible features of the component part fulfil in themselves the requirements as to novelty and individual character.

4. 'Normal use` within the meaning of paragraph (3)(a) shall mean use by the end user, excluding maintenance, servicing or repair work.

Article 4

Novelty

A design shall be considered new if no identical design has been made available to the public before the date of filing of the application for registration or, if priority is claimed, the date of priority. Designs shall be deemed to be identical if their features differ only in

immaterial details.

Article 5

Individual character

1. A design shall be considered to have individual character if the overall impression it produces on the informed user differs from the overall impression produced on such a user by any design which has been made available to the public before the date of filing of the application for registration or, if priority is claimed, the date of priority.

2. In assessing individual character, the degree of freedom of the designer in developing the design shall be taken into consideration.

Article 6

Disclosure

1. For the purpose of applying Articles 4 and 5, a design shall be deemed to have been made available to the public if it has been published following registration or otherwise, or exhibited, used in trade or otherwise disclosed, except where these events could not reasonably have become known in the normal course of business to the circles specialised in the sector concerned, operating within the Community, before the date of filing of the application for registration or, if priority is claimed, the date of priority. The design shall not, however, be deemed to have been made available to the public for the sole reason that it has been disclosed to a third person under explicit or implicit conditions of confidentiality.

2. A disclosure shall not be taken into consideration for the purpose of applying Articles 4 and 5 if a design for which protection is claimed under a registered design right of a Member State has been made available to the public:
(a) by the designer, his successor in title, or a third person as a result of information provided or action taken by the designer, or his successor in title; and
(b) during the 12-month period preceding the date of filing of the application or, if priority is claimed, the date of priority.

3. Paragraph 2 shall also apply if the design has been made available to the public as a consequence of an abuse in relation to the designer or his successor in title.

Article 7

Designs dictated by their technical function and designs of interconnections

1. A design right shall not subsist in features of appearance of a product which are solely dictated by its technical function.

2. A design right shall not subsist in features of appearance of a product which must necessarily be reproduced in their exact form and dimensions in order to permit the product in which the design is incorporated or to which it is applied to be mechanically connected to or placed in, around or against another product so that either product may perform its function.

3. Notwithstanding paragraph 2, a design right shall, under the conditions set out in Articles 4 and 5, subsist in a design serving the purpose of allowing multiple assembly or connection of mutually interchangeable products within a modular system.

Article 8

Designs contrary to public policy or morality

A design right shall not subsist in a design which is contrary to public policy or to accepted principles of morality.

Article 9

Scope of protection

1. The scope of the protection conferred by a design right shall include any design which does not produce on the informed user a different overall impression.

2. In assessing the scope of protection, the degree of freedom of the designer in developing his design shall be taken into consideration.

Article 10

Term of protection

Upon registration, a design which meets the requirements of Article 3(2) shall be protected by a design right for one or more periods of five years from the date of filing of the application. The right holder may have the term of protection renewed for one or more periods of five years each, up to a total term of 25 years from the date of filing.

Article 11

Invalidity or refusal of registration

1. A design shall be refused registration, or, if the design has been registered, the design right shall be declared invalid:
(a) if the design is not a design within the meaning of Article 1(a); or
(b) if it does not fulfil the requirements of Articles 3 to 8; or
(c) if the applicant for or the holder of the design right is not entitled to it under the law of the Member State concerned; or

(d) if the design is in conflict with a prior design which has been made available to the public after the date of filing of the application or, if priority is claimed, the date of priority, and which is protected from a date prior to the said date by a registered Community design or an application for a registered Community design or by a design right of the Member State concerned, or by an application for such a right.

2. Any Member State may provide that a design shall be refused registration, or, if the design has been registered, that the design right shall be declared invalid:
(a) if a distinctive sign is used in a subsequent design, and Community law or the law of the Member State concerned governing that sign confers on the right holder of the sign the right to prohibit such use; or
(b) if the design constitutes an unauthorised use of a work protected under the copyright law of the Member State concerned; or
(c) if the design constitutes an improper use of any of the items listed in Article 6b of the Paris Convention for the Protection of Industrial Property, or of badges, emblems and escutcheons other than those covered by Article 6b of the said Convention which are of particular public interest in the Member State concerned.

3. The ground provided for in paragraph 1(c) may be invoked solely by the person who is entitled to the design right under the law of the Member State concerned.

4. The grounds provided for in paragraph 1(d) and in paragraph 2(a) and (b) may be invoked solely by the applicant for or the holder of the conflicting right.

5. The ground provided for in paragraph 2(c) may be invoked solely by the person or entity concerned by the use.

6. Paragraphs 4 and 5 shall be without prejudice to the freedom of Member States to provide that the grounds provided for in paragraphs 1(d) and 2(c) may also be invoked by the appropriate authority of the Member State in question on its own initiative.

7. When a design has been refused registration or a design right has been declared invalid pursuant to paragraph 1(b) or to paragraph 2, the design may be registered or the design right maintained in an amended form, if in that form it complies with the requirements for protection and the identity of the design is retained. Registration or maintenance in an amended form may include registration accompanied by a partial disclaimer by the holder of the design right or entry in the design Register of a court decision declaring the partial invalidity of the design right.

8. Any Member State may provide that, by way of derogation from paragraphs 1 to 7, the grounds for refusal of registration or for invalidation in force in that State prior to the date on which the provisions necessary to comply with this Directive enter into force shall apply to design applications which have been made prior to that date and to resulting registrations.

9. A design right may be declared invalid even after it has lapsed or has been surrendered.

Article 12

Rights conferred by the design right

1. The registration of a design shall confer on its holder the exclusive right to use it and to prevent any third party not having his consent from using it. The aforementioned use shall cover, in particular, the making, offering, putting on the market, importing, exporting or using of a product in which the design is incorporated or to which it is applied, or stocking such a product for those purposes.

2. Where, under the law of a Member State, acts referred to in paragraph 1 could not be prevented before the date on which the provisions necessary to comply with this Directive entered into force, the rights conferred by the design right may not be invoked to prevent continuation of such acts by any person who had begun such acts prior to that date.

Article 13

Limitation of the rights conferred by the design right

1. The rights conferred by a design right upon registration shall not be exercised in respect of:
(a) acts done privately and for non-commercial purposes;
(b) acts done for experimental purposes;
(c) acts of reproduction for the purposes of making citations or of teaching, provided that such acts are compatible with fair trade practice and do not unduly prejudice the normal exploitation of the design, and that mention is made of the source.

2. In addition, the rights conferred by a design right upon registration shall not be exercised in respect of:
(a) the equipment on ships and aircraft registered in another country when these temporarily enter the territory of the Member State concerned;
(b) the importation in the Member State concerned of spare parts and accessories for the purpose of repairing such craft;
(c) the execution of repairs on such craft.

Article 14

Transitional provision

Until such time as amendments to this Directive are adopted on a proposal from the Commission in accordance with the provisions of Article 18, Member States shall maintain in force their existing legal provisions relating to the use of the design of a component part used for the purpose of the repair of a complex product so as to restore its

original appearance and shall introduce changes to those provisions only if the purpose is to liberalise the market for such parts.

Article 15

Exhaustion of rights

The rights conferred by a design right upon registration shall not extend to acts relating to a product in which a design included within the scope of protection of the design right is incorporated or to which it is applied, when the product has been put on the market in the Community by the holder of the design right or with his consent.

Article 16

Relationship to other forms of protection

The provisions of this Directive shall be without prejudice to any provisions of Community law or of the law of the Member State concerned relating to unregistered design rights, trade marks or other distinctive signs, patents and utility models, typefaces, civil liability or unfair competition.

Article 17

Relationship to copyright

A design protected by a design right registered in or in respect of a Member State in accordance with this Directive shall also be eligible for protection under the law of copyright of that State as from the date on which the design was created or fixed in any form. The extent to which, and the conditions under which, such a protection is conferred, including the level of originality required, shall be determined by each Member State.

Article 18

Revision

Three years after the implementation date specified in Article 19, the Commission shall submit an analysis of the consequences of the provisions of this Directive for Community industry, in particular the industrial sectors which are most affected, particularly manufacturers of complex products and component parts, for consumers, for competition and for the functioning of the internal market. At the latest one year later the Commission shall propose to the European Parliament and the Council any changes to this Directive needed to complete the internal market in respect of component parts of complex products and any other changes which it considers necessary in light of its consultations with the parties most affected.

Article 19

Implementation

1. Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive not later than 28 October 2001.
When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field governed by this Directive.

Article 20

Entry into force

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Communities.

Article 21

Addressees

This Directive is addressed to the Member States.